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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,231	01/23/2004	Gerald T. Gourdin	HAU234 CIP2	8493

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EXAMINER

OH, TAYLOR V

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/764,231

Applicant(s)

GOURDIN ET AL.

Examiner

Taylor Victor Oh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 8/1/05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 26-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25 and 30-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 9/21/04 & 1/23/04 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/26/04</u> . | 6) <input type="checkbox"/> Other: _____  |

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**The Status of claims :**

*Claims 1-33 are pending.*

*Claims 1-25 and 30-33 have been rejected.*

*Claims 26-29 have been withdrawn.*

***Election/Restrictions***

Applicant's election without traverse of Group I (claims 1-25 and 30-33 ) on 8/1/05 is acknowledged.

Claims 26-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group II, there being no allowable generic or linking claim.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-25 and 30-33, and their dependent claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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In claims 1 and 30, the phrase "substantially depleted levels" is recited. This expression is indefinite and vague because the specification and the claim do not explain what the substantially depleted levels of the non-phenolic compounds can be in the composition. Therefore, an appropriate correction is required.

In claim 1, the phrase "one or more electron-withdrawing groups" is recited. This expression is indefinite and vague because this does not elaborate what the electron-withdrawing groups are composed of and what the upper limit of the electron-withdrawing groups the resin can have during the process. Therefore, an appropriate correction is required.

In claims 1 and 30, the phrase "substantially" is recited. This expression is indefinite and vague because the specification and the claim do not explain what it is meant by the term "substantially". Therefore, an appropriate correction is required.

In claims 21-22, the phrase "substantially free of anthocyanins" is recited. This expression is indefinite and vague because the specification and the claim do not explain what it is meant by the term "substantially free of anthocyanins". It is questionable that how much free of anthocyanins in the composition is substantially free of anthocyanins. Therefore, an appropriate correction is required.

***Claim Rejections - 35 USC § 103***

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-19 and 30-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gabetta et al (U.S. 5,200,186) in view of Langston (U.S. 4,500,556) and S.O.R.I.(GB 1,235,379).

Gabetta et al discloses a commercial *Vaccinium myrtillus* extract contains 35 % of anthocyanosides (see col. 3 ,lines 45-46) , which can be used in a therapy in the pathology of capillaries and in the ophthalmology (see coil. 1 ,lines 12-15). Besides anthocyanosides and aglycones (see col. 1 ,lines 16-18), it may have mineral salts, common organic acids, and etc. (see col. 1 ,lines 27-30).

Furthermore, Gabetta et al teaches a method of preparing a high concentration of anthocyanosides from the fruits of *Vaccinium myrtillus*, *Ribes nigrum*, *Vitis vinifera*, *Sambucus*, and other plants (see col. 1, 11-12) in the following steps of :

- a. extracting *Vaccinium myrtillus* fruits with 50 % aqueous methanol;
- b. adding sodium bisulfite to the solution;
- c. charging the solution to a non-polar polystyrenic resin;
- d. washing the column with 8 liter of water, thereby eluting anthocyanosides;
- e. concentrating the eluted aqueous solution under vacuum;
- f. acidifying the aqueous solution with 1% hydrochloric acid solution;
- g. extracting the aqueous solution with butanol;
- h. washing the resultant solution with HCl solution; and

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i. precipitating the solid and being dried under vacuum (see col. 3, example 1).

As a result of the process, the extract of anthocyanosides contains the following composition (%): delphinidin galactoside 13.20, delphinidin glucoside 15.00, delphinidin arabinoside 9.06, cyanidin galactoside 7.25, cyanidin glucoside 9.06, cyanidin arabinoside 4.41, petunidin galactoside 3.88, petunidin glucoside 9.07, petunidin arabinoside 1.94, peonidin galactoside 0.65, peonidin glucoside 3.45, peonidin arabinoside 0.24, malvidin galactoside 3.02, peonidin glucoside 9.06, peonidin arabinoside 0.95 (see col. 3 ,lines 30-40).

Furthermore, during the extracting step, a polar organic solvent immiscible with water is used(see col. 3 ,lines 30-40).

The instant invention ,however, differs from the Gabetta et al reference in that the two sequential eluting steps have been conducted ; the claimed resin is a protonated tertiary amine-substituted styrene divinylbenzene copolymer ; pectinase is present in the extract; the resultant composition comprises at least from 12 to 25 % total phenols.

Langston teaches a process of anthocyanin colorant from grape pomace in the following procedure:

a. contacting grape pomace with an aqueous extraction solvent containing  $\text{HSO}_3^-$  ions to extract an anthocyanin-bisulfite ion adduct;

- b. removing the aqueous extraction solvent and undissolved solids from the grape pomace by filtration;
- c. contacting the aqueous extraction solvent with a non-ionic adsorbent to adsorb the anthocyanin-bisulfite pigment complex;
- d. washing the adsorbent to remove soluble sugar, organic acid and other water soluble non-pigmented material; and
- e. eluting the anthocyanin from the adsorbent with an acidified organic solvent (see col. 2 ,lines 6-27).

In addition, during the process, the extract solution is filtered to remove undissolved solids in any convenient manner (see col. 3 ,lines 14-16) ; after filtering, the extract solution is contacted with a non-ionic adsorbent such as macroreticular styrene and divinylbenzene resin (see col. 3 ,lines 43-44).

Furthermore, S.O.R.I. discloses a process for extracting anthocyanines from certain berries and fruits by using extraction solvents, such as water ,methanol, ethanol or butanol or any mixture thereof (see page 2 , lines 32-35). During the process of yielding juice, pectinase can be added to the crushed fruits (see page 1, 39-45). Furthermore, the composition of the unpurified extract may contain 27 to 30 % of anthocyanins, traces of aglycone, monosaccharides, traces of pectins, and organic ions (see page 2 ,lines 55-68). The recovery of anthocyanins happens in the strong acidic medium, such as hydrochloric acid (see page 2 ,lines 75-81).



With respect to the two sequential eluting steps, this is directly related to the optimization of eluting steps. Furthermore, this does not have any patentable weight over the prior art reference. Therefore, it would have been obvious to the skillful artisan in the art to have motivated to optimize the eluting steps by routine experimentations in order to enhance the process .

Concerning the use of the protonated tertiary amine-substituted styrene divinylbenzene copolymer in the process, Gabetta et al does indicate the broad use of the non-polar polystyrenic resin and Langston expressly teaches the use of macroreticular styrene and divinylbenzene resin to which the protonated tertiary amine-substituted styrene divinylbenzene copolymer resin may be belonged. Furthermore, there is little difference between their respective functionalities during the purification processes. Furthermore, this does not have any patentable weight over the prior art reference. Therefore, it would have been obvious to the skillful artisan in the art to have motivated to use as an alternative in order to enhance the process .

All three references have commonly shared the process of preparing the high concentration of anthocyanosides from the fruit by means of extraction and ion exchange resins. Gabetta et al does teach the general method of preparing the high concentration of anthocyanosides from the various fruits by extracting the fruits containing anthocyanines in the presence of the polar organic solvent by means of the non-polar polystyrenic resin. Langston does indicate that after filtering, the extract

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solution is contacted with the non-ionic adsorbent. And S.O.R.I. does point out that the pre-concentrated liquid and juice may be purified by means of ion exchange resins to form anthocyanin cations in the strong acidic medium. Therefore, it would have been obvious to the skillful artisan in the art to be motivated to incorporate Langston's filtration step prior to contacting ion exchange resins in the Gabetta et al process ,along with the use of S.O.R.I.'s strong acidic medium , thereby enhancing the purification process of anthocyanins. This is because the skilled artisan in the art would expect the combined processes to increase the purity of the desired compound as well as to have a similar success as shown in the S.O.R.I. process.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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